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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,363	09/06/2005	Kathryn Elizabeth Lawlor	18688	5197
272 7590 06/07/2010 SCULLY, SCOTT, MURPHY & PRESSER, P.C. 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530				
EXAMINER				
WOODWARD, CHERIE MICHELLE				
ART UNIT		PAPER NUMBER		
1647				
MAIL DATE		DELIVERY MODE		
06/07/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary

Application No.

10/525,363

Applicant(s)

LAWLOR ET AL.

Examiner

CHERIE M. WOODWARD

Art Unit

1647

All participants (applicant, applicant's representative, PTO personnel):

(1) Cherie M. Woodward.(3) Gary Nickol.(2) Frank DiGilio.

(4) ____.

Date of Interview: 5/19/10 & 5/24/10.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal (copy given to: 1) ☐ applicant 2) ☐ applicant's representative)

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: ____.

Claim(s) discussed: All pending.

Identification of prior art discussed: All cited.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: A telephonic interview was held with Applicant's representative Frank DiGiglio, the examiner, and the examiner's supervisor, Gary Nickol on 5/19/2010. The interview focused on Applicant's argument that the prior art was not enabled. The Declaration of co-inventor Wicks was also discussed. Applicant argues that only a presentation of animal data showing in vivo use would enable the prior art. No agreement was reached, but the examiner stated that she would further review the case and the prior art and would follow up with Applicant's representative.

The examiner contacted Applicant's representative on 5/24/2010 as a follow-up and discussed the following: The cited 102(e) reference teaches methods of treating arthritis using antibodies to G-CSF. However, in vivo experiments as to G-CSF are not specifically disclosed. During the prosecution of the prior art case (a patent application publication which has since issued as a US Patent, directed to the use of M-CSF, a related growth factor affecting myeloid cells) does not mean that the method of treating arthritis using an antibody to G-CSF, G-CSF-R or soluble G-CSF or G-CSF-R is not enabled per se. Whether something is enabled requires an analysis of whether there is an adequate teaching of how to make and use it, such that the quid-pro-quo exchange of disclosure for a limited-time government-sanctioned monopoly (a patent) is met. The rationale for the enablement requirement is that an inventor deprives the public of nothing which it enjoyed before his discovery, but gives something of value to the community by adding to the sum of human knowledge. He may keep his invention secret and reap its fruits indefinitely. In consideration of its disclosure and the consequent benefit to the community, the patent is granted.

When considering whether a prior art reference (or any reference) is enabled, the examiner and the applicant are required to consider the factors set forth in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (*Wands factors*). The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability, 5) existence of working samples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention.

The state of the art at the time of the instant invention as well as the predictive nature of the art using related growth factors, including the M-CSF taught by the cited prior art reference and GM-CSF in the treatment of arthritis, in the treatment of arthritis made the instant method of treatment predictable and it would have been able to be practiced without undue experimentation. Undue experimentation does not mean that no experimentation is required to practice the claimed invention. Some amount of routine experimentation is permissible. For example, experiments using animal models are routinely accepted as being adequate models of applicability of use of the methods in humans, even though no human experimentation is actually shown.

The instant Declaration of co-inventor Wicks states that the experiments performed in the cited prior art reference aren't predictive of the outcome of treatment of arthritis. This argument is not persuasive. A person of ordinary skill in the art at the time of the instantly claimed invention would have recognized that the prior art teaches antibodies against GM-CSF and M-CSF (closely related growth factors) that are useful in treating arthritis. Both Applicant's representative and co-inventor Wicks recognize that the cited 102(e) prior art reference provides in vivo experimental data to this effect using M-CSF (see the prosecution history of the 102(e) reference). Additionally, Cook et al., (*Arthritis Res.* 11 June 2001;3:293-298) (Univ of Melbourne) teach in vivo models of treating collagen-induced arthritis using antibodies against GM-CSF. Both of these references provide detailed methodologies and provide evidence of predictability if one to follow their protocols using a related growth factor, G-CSF.

Additionally, the general dogma of clinical immunology suggests that the suppression of upregulated pro-inflammatory cytokines and growth factors related to the upregulation of pro-inflammatory cytokines (in this case G-CSF upregulates IL-8) will treat or reduce symptoms of inflammatory disorders, including arthritis.

Further, as cited of record, after-filed art clearly shows that arthritis may be treated using antibodies to G-CSF. This after-filed art provides additional evidence that the method of the cited prior art reference is enabled and does work as recited in the 102(e) prior art reference.

Applicants have not provided any specific evidence that the instantly claimed invention could not have been successfully performed with the art-known models at the time the instant invention was made, especially in view of the fact that similar growth factors, affecting the same and similar granulocyte lineages, have been used successfully. Undue experimentation, the critical test in an enablement analysis, simply cannot be found in light of the prior art, which teaches the instant method and provides in vivo evidence showing that antibodies against M-CSF and GM-CSF work to treat arthritis and after-filed art also mitigates against a finding that undue experimentation would have been required. These prior art references, the general immunological dogma, and in vivo studies show a solid degree of predictability in using antibodies against G-CSF to treat arthritis. Absent evidence to the contrary, the prior art reference is enabled in teaching antibodies against G-CSF to treat arthritis.